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10/028,346	12/20/2001	Meilina Ong Abdullah	15179	3064

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/028,346	ABDULLAH ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,34-61 and 72* is/are pending in the application.

4a) Of the above claim(s) *34-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed August 19, 2009 has been entered.

Claims 27-33 and 62-71 are cancelled.

Claims 34-61 are withdrawn.

Claims 1, 8, 18 and 72 are currently amended.

Claims 1-26, 34-61 and 72 are pending.

Claims 1-26 and 72 are examined.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8 and 18, and claims 2-7, 9-17 and 19-26 dependent thereon, remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record.

Applicant's arguments filed August 19, 2009 have been fully considered but they are not persuasive.

Applicant maintains that although the specification makes reference to nucleotide sequences at page 18, line 6, "similarity" is clearly described as referring to exact identity at the nucleotide or amino acid level at page 18, lines 12-13. Applicant accordingly submits that the specification equally describes similarity at 80% and beyond at the

nucleotide and amino acid level sufficient for compliance with the provisions of 35 U.S.C. §I 12, first paragraph. (reply page 12).

This is not persuasive as the specification page 18, lines 12-13 makes no reference to encoded polypeptides comprising an amino acid sequence having at least similarity 80% identity to SEQ ID NO: 2. Further, similarity at the nucleotide level is not equivalent to similarity at the amino acid level.

Claims 1-4, 8-21, 25-26, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The rejected claims require the presence of a broad genus of isolated nucleic acid molecules that encode a polypeptide comprising any amino acid sequence as set forth in SEQ ID NO:2 or an amino acid sequence having at least 80% identity to SEQ ID NO:2, wherein the nucleic acid permits discrimination of plant tissue at different developmental stages, including isolated nucleic acid molecules that comprise any sequence of nucleotides as set forth in SEQ ID NO:1 or SEQ ID NO:3 or its complementary form, isolated nucleic acid molecules that have at least about 71% identity to SEQ ID NO:1 or SEQ ID NO:3 or its complementary form, isolated nucleic acid molecules that are capable of hybridizing to SEQ ID NO:1 or SEQ ID NO:3 or its complementary form under low stringency conditions, and isolated nucleic acid molecules that are substantially as set forth in SEQ ID

NO:1 or SEQ ID NO:3 or its complementary form. The rejected claims also require the presence of a broad genus of isolated nucleic acid molecules that encode a polypeptide and that comprise a nucleotide sequence capable of hybridizing to SEQ ID NO:1 or SEQ ID NO:3 or its complementary form under defined stringency conditions, wherein the nucleic acid permits discrimination of plant tissue at different developmental stages.

In contrast, the specification describes a single type of isolated nucleic acid that meets both the structural and functional limitations of the claims, an isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO:3, a full length cDNA obtained from oil palm *(Elaeis oleifera)* whose open reading frame (SEQ ID NO:1) encodes a polypeptide having the amino acid sequence of SEQ ID NO:2 (identical to SEQ ID NO:4) (pages 45- 46 Example 1; page 49 Example 4; sequence listing). This type of isolated nucleic acid permits detection of embryogenic calli, suspension cultures, embryoids up to somatic embryos in the form of 20 bipolar structures and zygotic embryo (pages 47-49 examples 3 and 4). The specification does not describe other isolated nucleic acid molecules that differ in structure from SEQ ID NOS: 1 and 3 that encode a polypeptide and that permit discrimination of plant tissue at different developmental stages. The specification also does not describe the structural features of SEQ ID NOS: 1 and 3 that are critical to the function of discriminating plant tissue at different developmental stages. Accordingly, Applicant has not described a representative number of species falling within the scope of the broad genus of isolated nucleic acid molecules required by the rejected claims, nor the structural features unique to the genus that are correlated with the discrimination of plant tissue at different developmental stages.

Claims 1-4, 8-21, 25-26 and 72 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding a polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 2, does not reasonably provide enablement for isolated nucleic acid molecules encoding polypeptides comprising other amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments filed August 19, 2009 have been fully considered but they are not persuasive.

Applicant submits that the sequence analysis exemplified at Examples 2-6 and the sequence alignments provide a roadmap to guide the skilled artisan how to alter the amino acid of e.g. SEQ ID NO:2 without changing its specific function, and that that any additional sequence analysis and peroxiredoxin activity testing would not be undue and would be performed within the ken of the skilled artisan (reply pages 12-13).

Applicant's arguments are not persuasive as the claims as currently amended are broadly drawn to isolated nucleic acid molecules that encode a polypeptide comprising any amino acid sequence as set forth in SEQ ID NO:2 or an amino acid sequence having at least 80% identity to SEQ ID NO:2, wherein the nucleic acid permits discrimination of plant tissue at different developmental stages, including isolated nucleic acid molecules that comprise any sequence of nucleotides as set forth in SEQ ID NO:1 or SEQ ID NO:3 or its complementary form, isolated nucleic acid molecules that have at least about 71% identity to SEQ ID NO:1 or SEQ ID NO:3 or its complementary form, isolated nucleic

acid molecules that are capable of hybridizing to SEQ ID NO:1 or SEQ ID NO:3 or its complementary form under low stringency conditions, and isolated nucleic acid molecules that are substantially as set forth in SEQ ID NO:1 or SEQ ID NO:3 or its complementary form, and to genetic constructs, vectors and host cells comprising the isolated nucleic acid molecules. The claims as currently amended are also broadly drawn to isolated nucleic acid molecules that encode a polypeptide and that comprise a nucleotide sequence capable of hybridizing to SEQ ID NO:1 or SEQ ID NO:3 or its complementary form under defined stringency conditions, wherein the nucleic acid permits discrimination of plant tissue at different developmental stages.

The specification discloses how to use a single type of isolated nucleic acid that meets the structural limitations of the claims, an isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO:3, a full length cDNA obtained from oil palm *(Elaeis oleifera)* whose open reading frame (SEQ ID NO:1) encodes a polypeptide having the amino acid sequence of SEQ ID NO:2 (identical to SEQ ID NO:4) (pages 45- 46 Example 1; page 49 Example 4; sequence listing). This type of isolated nucleic acid was used to detect by Northern hybridization the expression of the corresponding gene in embryogenic calli, suspension cultures, embryoids up to somatic embryos in the form of 20 bipolar structures and zygotic embryo (pages 47-49 examples 3 and 4).

The specification does not disclose how to use other isolated nucleic acid molecules that differ in structure from SEQ ID NOS: 1 and 3 that encode a polypeptide to detect by Northern hybridization the expression of the corresponding gene in embryogenic calli, suspension cultures, embryoids up to somatic embryos in the form of 20 bipolar

structures and zygotic embryo of oil palm *(Elaeis oleifera)*. The specification also does not disclose how to use SEQ ID NO:1 or SEQ ID NO:3, or other isolated nucleic acid molecules that differ in structure from SEQ ID NOS: 1 and 3 that encode a polypeptide, to discriminate developmental stages in other types of plant tissue or in other plant species.

The full scope of the claimed invention is not enabled because the conditions for using an isolated nucleic acid to discriminate plant tissue at different developmental stages are unpredictable, since the conditions under which an isolated nucleic acid will hybridize to a target sequence vary and depend in part on the specific sequence of the probe and target.

See, for example, Gillespie D. (The magic and challenge of DNA probes as diagnostic reagents. Vet Microbiol. 1990 Sep;24(3-4):217-33. Review), who teaches that specific hybridization between a DNA probe and its target sequence are affected by conditions such as the concentration of probe and target molecules, the length and sequence of the probe, the hybridization temperature, and the concentration of the salt and detergent present during hybridization (abstract; pages 220-222).

See also, for example, Stacy R.A. et al. (A peroxiredoxin antioxidant is encoded by a dormancy-related gene, Per1, expressed during late development in the aleurone and embryo of barley grains. Plant Molecular Biology. 1996, **31:** 1205–1216), who teach that under their standard hybridization conditions (68° C, 1XSSC), the 2-Cys barley peroxiredoxin transcript will not cross-hybridize with barley peroxiredoxin Per1 probes (page 1208 column 2 first paragraph).

In the instant case the specification does not provide sufficient guidance with respect to which isolated nucleic acids to use to discriminate plant tissue at different developmental stages, the conditions for their use, and the specific targets that can be detected using these probes. Absent such guidance one skilled in the art would have to test each of the myriad sequences encompassed by the claims under a variety of different conditions against a variety of different samples in order to determine which isolated nucleic acids are useful for the detection of particular target sequences and which are not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lewis M.L. et al. (FePer 1, a gene encoding an evolutionarily conserved 1-Cys peroxiredoxin in buckwheat (*Fagopyrum esculentum* Moench), is expressed in a seed-specific manner and induced during seed germination. Gene. 2000 Apr 4;246(1-2):81-91, and GenBank Accession No. AF191099, *Fagopyrum esculentum* 1-Cys peroxiredoxin (Per1) mRNA, complete cds., April 24, 2000), for the reasons of record.

Applicant's arguments filed August 19, 2009 have been fully considered but they are not persuasive.

Applicant submits that the nucleic acid molecule taught by Lewis does not encode a protein having at least 80% sequence identity with SEQ ID NO: 2 wherein the nucleic acid permits discrimination of plant tissue at different developmental stages, as presently claimed, and therefore does not teach each and every element of the claimed nucleic acid molecule. Applicant further submits that Lewis does not teach or suggest a nucleic acid molecule comprising a nucleotide sequence having at least 85% or 95% sequence identity with SEQ ID NO: 1 or 3 wherein the nucleic acid permits discrimination of plant tissue at different developmental stages as presently claimed (reply page 14).

Applicant's arguments are unpersuasive as Lewis M.L. et al. teach a nucleic acid molecule that encodes a protein comprising an amino acid sequence as set forth in SEQ ID NO: 2, e.g. the nucleic acid molecule taught by Lewis M.L. et al. encodes a protein comprising amino acids 1-8 of SEQ ID NO: 2.

Applicant's arguments are also unpersuasive as Lewis M.L. et al. teach a nucleotide sequence having at least 85% or 95% sequence identity with SEQ ID NO: 1 or 3, e.g. the nucleic acid molecule taught by Lewis M.L. et al. comprises nucleotides 1-5 of SEQ ID NO: 1, which sequence has 100% sequence identity with SEQ ID NO: 1.

Applicant's arguments are additionally unpersuasive as Lewis M.L. et al. teach temporal regulation of the expression of the FePer 1 gene during seed development, which permits the nucleic acid to discriminate of plant seed tissue at different developmental stages (page 88 Figures 5-7; page 90 column 1).

The amendment of claims 1, 8 and 18 to replace the phrase "an amino acid sequence as set forth in SEQ ID NO:2" with the phrase "the amino acid sequence as set forth in SEQ ID NO:2", and the amendment of claims 2, 12, 13 and 19 to replace the phrase "a sequence of nucleotides as set forth in SEQ ID NO:1" with the phrase "the sequence of nucleotides as set forth in SEQ ID NO:1", and the amendment of claim 14 to replace the phrase "a sequence of nucleotides as set forth in SEQ ID NO:1" with the phrase "the sequence of nucleotides as set forth in SEQ ID NO:3", and the amendment of claim 9 to replace the phrase "is substantially as set forth in SEQ ID NO:1" with the phrase "comprises the sequence of nucleotides as set forth in SEQ ID NO:1", would overcome the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis M.L. et al. (FePer 1, a gene encoding an evolutionarily conserved 1-Cys peroxiredoxin in buckwheat (*Fagopyrum esculentum* Moench), is expressed in a seed-specific manner and induced during seed germination. Gene. 2000 Apr 4;246(1-2):81-91) in view of Lee K.O. et al. (Rice 1Cys-peroxiredoxin over-expressed in transgenic tobacco does not maintain dormancy but enhances antioxidant activity. FEBS Lett. 2000 Dec

8;486(2):103-6) and Parveez G.K.A. et al. (Transgenic oil PALM: production and projection. Biochemical Society Transactions, 2000, 28(6):969-972), for the reasons of record.

Applicant's arguments filed August 19, 2009 have been fully considered but they are not persuasive.

Applicant submits that the nucleic acid molecule taught by Lewis does not encode a protein having at least 80% sequence identity with SEQ ID NO: 2 wherein the nucleic acid permits discrimination of plant tissue at different developmental stages, as presently claimed, and therefore does not teach each and every element of the claimed nucleic acid molecule. Applicant further submits that Lewis does not teach or suggest a nucleic acid molecule comprising a nucleotide sequence having at least 85% or 95% sequence identity with SEQ ID NO: 1 or 3 wherein the nucleic acid permits discrimination of plant tissue at different developmental stages as presently claimed (reply page 15).

Applicant's arguments are unpersuasive as Lewis M.L. et al. teach a nucleic acid molecule that encodes a protein comprising an amino acid sequence as set forth in SEQ ID NO: 2, e.g. the nucleic acid molecule taught by Lewis M.L. et al. encodes a protein comprising amino acids 1-8 of SEQ ID NO: 2.

Applicant's arguments are also unpersuasive as Lewis M.L. et al. teach a nucleotide sequence having at least 85% or 95% sequence identity with SEQ ID NO: 1 or 3, e.g. the nucleic acid molecule taught by Lewis M.L. et al. comprises nucleotides 1-5 of SEQ ID NO: 1, which sequence has 100% sequence identity with SEQ ID NO: 1.

Applicant's arguments are additionally unpersuasive as Lewis M.L. et al. teach temporal regulation of the expression of the FePer 1 gene during seed development, which permits the nucleic acid to discriminate of plant seed tissue at different developmental stages (page 88 Figures 5-7; page 90 column 1).

The amendment of claims 1, 8 and 18 to replace the phrase "an amino acid sequence as set forth in SEQ ID NO:2" with the phrase "the amino acid sequence as set forth in SEQ ID NO:2", and the amendment of claims 2, 12, 13 and 19 to replace the phrase "a sequence of nucleotides as set forth in SEQ ID NO:1" with the phrase "the sequence of nucleotides as set forth in SEQ ID NO:1", and the amendment of claim 14 to replace the phrase "a sequence of nucleotides as set forth in SEQ ID NO:1" with the phrase "the sequence of nucleotides as set forth in SEQ ID NO:3", and the amendment of claim 9 to replace the phrase "is substantially as set forth in SEQ ID NO:1" with the phrase "comprises the sequence of nucleotides as set forth in SEQ ID NO:1", would overcome the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer

Service Representative or access to the automated information system, call 800-786-9199

(IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC